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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/898,458 | 07/05/2001 | David Frederick Horrobin | P66731US0 | 8131 |

7590 01/26/2004

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| EXAMINER |
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CHANNAVAJALA, LAKSHMI SARADA

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,458

Applicant(s)

HORROBIN, DAVID FREDERICK

Examiner

Lakshmi S Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-49 is/are pending in the application.
- 4a) Of the above claim(s) 10-21 and 31-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 and 43-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of request for extension of time and amendment A both dated 9-25-03 is acknowledged. Claims 1-9 have been canceled and new claims 43-49 have been added. Accordingly, claims 10-49 are pending, of which claims 10-21 and 31-42 are withdrawn from consideration as being non-elected group. Accordingly, claims 22-30 and 43-49 are considered prosecution.

The following rejection of paper # 11 has been maintained:

1. Claims 22-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The newly presented claims 43-49 are also included in this rejection for the reasons mentioned in the previous action.

Applicants argue the amendment to claims to include only premenstrual or menstrual disorders, skin disorders and bone or calcium disorders, including osteoporosis have adequate support. Further, applicants state that because claim 29 recites consists essentially of, the rejection should be withdrawn. Applicants' arguments have been considered but not found persuasive because claim still covers a wide variety of diseases and disorders other than specifically claimed. The term "including," allows for diseases or disorders other than claimed. Further, applicants have not addressed the issue of "preventing" the diseases or disorders. Instant specification does not provide any teaching or suggestion if a complete success is achieved in preventing "a variety of diseases or disorders" by administering instant combination of Vitamin K and essential fatty acids. If

Art Unit: 1615

applicants desire to claim specific treatment, applicants are advised to state the diseases or disorders in a markush format. Accordingly, the rejection has been maintained.

2. Claims 22, 25, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,719,134 to Schmidl et al (Schmidl).

Response: Applicants argue that the amended claim recites the specific diseases and disorders and that claim 29 recites ‘consisting essentially of’, defining that the EFA and vitamin K are the essential active ingredients of the claims. Applicants state that Schmidl discloses a nutritional dietary composition for adolescents that includes carbohydrate, lipid and amino acid components, but insignificant amounts of vitamin K and EFA, thus suggesting that the claimed components are not essential for the composition of Schmidl. Applicants’ arguments are not persuasive because the term ‘consisting essentially of’ is open to the other components of Schmidl unless otherwise shown that the components affect the basic and novel characteristics of the instant composition. Further, as explained above, the amendment to claim 22 still includes other diseases other than claimed because of the language “including”. As explained in the previous action, the amounts of vitamin K and EFA in Schmidl are within the claimed range.

3. Claims 23, 24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,719,134 to Schmidl et al (Schmidl) in view of US 4,977,187 (‘187).

Art Unit: 1615

Applicants argue that there is no motivation or suggestion to combine the references and that the references teach away from the instant invention. Applicants once again present the argument that amended claim 22 recites specific disorders not taught by Schmidl and instead the reference teaches for conditions such as inflammatory bowel disease, lactose intolerance, short bowel syndrome etc. Further, applicants argue that the secondary reference ('187) teaches specifically schizophrenia and associative tardive dyskinesia and that neither reference provides a suggestion or incentive to combine these two references. Applicants' arguments have been considered but not found persuasive because, as explained before, the amended claim language does not exclude other diseases and instead includes a variety of diseases. Further, while it is true that Schmidl teaches nutritional composition comprising the claimed components for inflammatory bowel diseases etc., '187 teaches not only for schizophrenia but suggests using that the EFAs possess anti-oxidant activity useful for diseases such inflammatory bowel syndrome, cystic fibrosis (also taught by Schmidl), but also for skin diseases such eczema, psoriasis, premenstrual syndrome etc (col. 3, lines 30-40). Accordingly, the motivation to use the specific EFAs of '187 in the composition of Schmidl comes from the teaching of '187 that EFAs are effective for the same diseases such as those taught by Schmidl. Further, the motivation to use vitamin k and EFA containing composition of Schmidl to treat the claimed skin disorders, premenstrual syndrome comes from the teaching of '187.

Newly added claims 43-49 are also rejected under this section for the same reasons given previously.

Art Unit: 1615

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Lakshmi S Channavajjala
Examiner
Art Unit 1615
January 16, 2004


THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600